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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,597	04/13/2001	Tim Keith	2976-4039US1	4537

7590 06/17/2004

MORGAN & FINNEGAN, L.L.P.  
345 Park Avenue  
New York, NY 10154-0053

EXAMINER
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MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/834,597

**Applicant(s)**

KEITH ET AL.

**Examiner**

Carla Myers

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***RESTRICTION***

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-17, 43, 48-51, 58, 59, 84 and 85, drawn to wildtype human Gene 216 nucleic acids, classified in Class 536, subclass 23.5.

II. Claims 18-31, 51, 84 and 85, drawn to Gene 216 nucleic acids containing a polymorphism and Gene 216 splice variants, classified in Class 536, subclass 23.5.

III. Claims 32, 34-36, and 61, drawn to wildtype human proteins, classified in Class 530, subclass 350.

IV. Claim 33, drawn to proteins containing a polymorphism, classified in Class 530, subclass 350.

V. Claims 37, 39-40, 42, 52 and 60, drawn to antibodies to the human wildtype protein, classified in Class 530, subclass 387.1.

VI. Claims 38 and 41, drawn to antibodies to proteins containing a polymorphism, classified in Class 530, subclass 387.1.

VII. Claim 44, drawn to mouse Gene 216, classified in Class 536, subclass 23.5.

VIII. Claim 45, drawn to mouse Gene 216 protein, classified in Class 530, subclass 350.

IX. Claims 46 and 47, drawn to antibodies to the mouse wildtype protein, classified in Class 530, subclass 387.1.

X. Claims 53-56, drawn to a method to identify a Gene 216 ligand, classified in Class 435, subclass 7.2.

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XI. Claim 57, drawn to a Gene 216 ligand, Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the ligand).

XII. Claim 62, drawn to a method to identify Gene 216 or a Gene 215 ortholog, classified in Class 435, subclass 6.

XIII. Claims 63-64, drawn to methods of treatment with a ligand, Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the ligand).

XIV. Claims 65-68, drawn to methods of treatment with a nucleic acid, classified in Class 514, subclass 44.

XV. Claims 69 and 70, drawn to methods of treatment with an antibody, classified in Class 424, subclass 142.1.

XVI. Claims 71 and 72, drawn to methods of treatment with a protein, classified in Class 514, subclass 12.

XVII. Claims 73-77, drawn to transgenic animals, classified in Class 800, subclass 13.

XVIII. Claim 78, drawn to a method of forming a crystallized protein, classified in Class 435, subclass 69.1.

XIX. Claims 79 and 80, drawn to nucleic acid methods for detecting a chromosome 20 disorder, classified in Class 435, subclass 6.

XX. Claim 81, drawn to immunological methods for detecting a chromosome 20 disorder, classified in Class 435, subclass 7.1.

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XXI. Claim 82, drawn to methods of pharmacogenetic profiling nucleic acids, classified in Class 435, subclass 6.

XXII. Claim 83, drawn to methods for pharmacogenetic profiling proteins, classified in Class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and VII are patentably distinct in structure and physicochemical properties. Each of the inventions is drawn to a distinct nucleic acid molecule, such that each nucleic acid has its own unique chemical structure and its own unique functional features.

Inventions I and III, I and IV, I and VIII, II and III, II and IV, II and VIII, VII and III, VII and IV, and VII and VIII are patentably distinct in structure and physicochemical properties. Inventions I, II and VII are drawn to nucleic acids whereas inventions III, IV and VIII are drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of do not require the particular products of the nucleic acids of inventions I, II or VII since the proteins can be isolated from natural sources or chemically synthesized.

Inventions I and V, I and VI, I and IX, II and V, II and VI, II and IX, VII and V, VII and VI, and VII and IX are patentably distinct in structure and physicochemical properties. Inventions I, II and VII are drawn to nucleic acids whereas inventions V, VI

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and IX are drawn to antibodies. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while antibodies may be utilized in ligand binding assays. Synthesis of the antibodies does not require the particular products of the nucleic acids of inventions I, II or VII since the antibodies can be isolated from natural sources or chemically synthesized.

Inventions I and X, II and X and VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of inventions I, II and VII are not required to practice the ligand detection method of invention X.

Inventions I and XI, II and XI, and VII and XI are patentably distinct in structure and physicochemical properties. Inventions I, II and VII are drawn to nucleic acids whereas invention XI is drawn to ligands. Because nucleic acids are composed of nucleotides and ligands are composed of, for example, inorganic molecules or amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while ligands may be utilized in ligand binding assays or for therapeutic purposes. Synthesis of the ligands does not require the particular products of the nucleic acids of inventions I, II or VII since the ligands can be isolated from natural sources or chemically synthesized.

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Inventions I and XII, I and XIV, I and XIX, I and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions II and XI, II and XIX, VII and XI and VII and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific nucleic acids of inventions II and VII are not required to practice the method set forth in invention XI or XIX.

Inventions I and XIII, II and XIII, and VII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of inventions I, II and VII are not required to practice the ligand detection method of invention XIII.

Inventions II and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions VII and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific nucleic acids of inventions II and VII are not required to practice the method set forth in invention XXI.

Inventions I and XV, I and XVI, I and XVIII, I and XX, I and XXII, II and XV, II and XVI, II and XVIII, II and XX, II and XXII, Inventions VII and XV, VII and XVI, VII and XVIII, VII and XX, VII and XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of inventions I, II and VII are not required to practice the methods of inventions XV, XVI, XVIII, XX or XXII.

Inventions I and XVII, II and XVII and VII and XVII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animal is a patentably distinct entity over the nucleic acids since the



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transgenic animal has its own unique functional and structural characteristics. The subcombination has separate utility such as to serve as a template for DNA or RNA synthesis or as a probe in a hybridization assay.

Inventions III, IV and VIII are patentably distinct in structure and physicochemical properties. Each of the inventions is drawn to a distinct protein molecule, such that each protein has its own unique chemical structure and its own unique functional features.

Inventions III and V, III and VI, III and IX, IV and V, IV and VI, IV and IX, VIII and V, VIII and VI, and VIII and IX are patentably distinct in structure and physicochemical properties. Inventions III, IV and VIII are drawn to proteins whereas inventions V, VI and IX are drawn to antibodies. The proteins and antibodies differ in their primary amino acid sequence and in the secondary and tertiary structures. The proteins and antibodies also have different functional properties and can be utilized in different methodologies. Synthesis of the antibodies of inventions V, VI and IX does not require the particular products of the proteins of inventions III, IV or VIII since the antibodies can be isolated from natural sources or chemically synthesized.

Inventions III and X, III and XIII, III and XVI, III and XVIII, III and XX, III and XXII, IV and X, IV and XIII, IV and XVI, IV and XVIII, IX and XX, IV and XXII, VIII and X, and VIII and XIII, VIII and XVI, VIII and XVIII, VIII and XX, and VIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

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used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins can be used in a materially different process, such as for synthesizing antibodies.

Inventions III and XI, IV and XI, and VIII and XI are patentably distinct in structure and physicochemical properties. Inventions III, IV and VIII are drawn to nucleic acids whereas invention XI is drawn to ligands. Because proteins are composed of a specific sequence of amino acids and ligands are composed of, for example, inorganic molecules or a distinct sequence of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies. Synthesis of the ligands does not require the particular products of the proteins of inventions III, IV or VIII since the ligands can be isolated from natural sources or chemically synthesized.

Inventions III and XII, III and XIV, III and XIX, and III and XXI, IV and XII, IV and XIV, IV and XIX, and IV and XXI, VIII and XII, VIII and XIV, VIII and XIX, and VIII and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of inventions III, IV and VIII are not required to practice the nucleic acid methods of inventions XII, XIV, XIX and XXI.

Inventions III and XV, IV and XV, and VIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

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§ 806.04, MPEP § 808.01). In the instant case, the proteins of inventions III, IV and VIII are not required to practice the methods of invention XV.

Inventions III and XVII, IV and XVII, and VIII and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific proteins of inventions III, IV and VIII are structurally and functionally distinct from the transgenic animal of invention XVII and the proteins are not required to produce the transgenic animal of invention XVII.

Inventions III and X, III and XIII, III and XVI, III and XVIII, III and XX, III and XXII, IV and X, IV and XIII, IV and XVI, IV and XVIII, IX and XX, IV and XXII, VIII and X, and VIII and XIII, VIII and XVI, VIII and XVIII, VIII and XX, and VIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins can be used in a materially different process, such as for synthesizing antibodies.

Inventions III and XI, IV and XI, and VIII and XI are patentably distinct in structure and physicochemical properties. Inventions III, IV and VIII are drawn to nucleic acids whereas invention XI is drawn to ligands. Because nucleic acids are composed of nucleotides and ligands are composed of, for example, inorganic

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molecules or a distinct sequence of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies. Synthesis of the ligands does not require the particular products of the proteins of inventions III, IV or VIII since the ligands can be isolated from natural sources or chemically synthesized.

Inventions III and XII, III and XIV, III and XIX, and III and XXI, IV and XII, IV and XIV, IV and XIX, and IV and XXI, VIII and XII, VIII and XIV, VIII and XIX, and VIII and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of inventions III, IV and VIII are not required to practice the nucleic acid methods of inventions XII, XIV, XIX and XXI.

Inventions III and XV, IV and XV, and VIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of inventions III, IV and VIII are not required to practice the methods of invention XV.

Inventions III and XVII, IV and XVII, and VIII and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific proteins of inventions III, IV and VIII are structurally and functionally distinct from the transgenic

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animal of invention XVII and the proteins are not required to produced the transgenic animal of invention XVII.

Inventions V and X, VI and X, and IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of inventions V, VI and IX are not specifically required to practice the methods of invention X.

Inventions V and XI, VI and XI and IX and XI are patentably distinct in structure and physicochemical properties. Inventions V, VI and IX are drawn to antibodies whereas invention XI is drawn to ligands. Because antibodies are composed of a distinct amino acid sequence and ligands are composed of, for example, inorganic molecules or a distinct sequence of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies. Synthesis of the ligands does not require the particular products of the antibodies of inventions V, VI or IX since the ligands can be isolated from natural sources or chemically synthesized.

Inventions V and XII, V and XIV, V and XIX, V and XXI, VI and XII, VI and XIV, VI and XIX, and VI and XXI, IX and XII, IX and XIV, IX and XIX, and IX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

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antibodies of inventions V, VI and IX are not required to practice the nucleic acid methods of inventions XII, XIV, XIX and XXI.

Inventions V, VI and VIII are related to inventions XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies can be used in a materially different process, such as for diagnostic purposes.

Inventions V, VI and VIII are unrelated to inventions XVI and XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of inventions V, VI and IX are not required to practice the method of invention XVI or XVIII.

Inventions V, VI and VIII are related to inventions XX and XXII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies can be used in a materially different process, such as for therapeutic purposes.

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Inventions V and XVII, VI and XVII, and IX and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific antibodies of inventions V, VI and IX are structurally and functionally distinct from the transgenic animal of invention XVII and the antibodies are not required to produce the transgenic animal of invention XVII.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the ligands of invention XI can be used in a materially different process, such as for therapeutic purposes.

Inventions X, XII, XIII, XIV, XV, XVI, XVIII, XIX, XX, XXI and XXII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions X and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the ligands of invention XI can be used in a materially different process, such as for protein detection or drug screening purposes.

Invention XI is unrelated to inventions XII, XIV, XV, XVI, XVIII, XIX, XX, XXI, and XXII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention XI are not required to practice the nucleic acid detection method of inventions XII, XIV, XV, XVI, XVIII, XIX, XX, XXI, and XXII.

### **3. Polymorphism / Sequence Election Requirement Applicable to Invention II, IV, VI, XXI and XXII.**

Inventions II, IV, VI, XXI and XXII read on patentably distinct inventions drawn to multiple nucleic acid, protein and antibody sequences. The claims encompass polymorphic and splice variants of Gene 216, proteins encoded by this gene and antibodies to said proteins. The 48 polymorphisms set forth in Table 10, as well as the 13 splice variants of SEQ ID NO: 350-362 consist of distinct nucleotide sequences, and a further restriction is applied to each invention. Applicants must elect a single polymorphism or splice variant or one combination of polymorphisms to be examined.

It is noted that each of the polymorphic and splice variants constitute distinct chemical compounds and each has a distinct functional property. These sequences are



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thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XXII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently

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found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers  
June 15, 2004

  
CARLA J. MYERS  
PRIMARY EXAMINER